IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) :

Chamberlain R., et al.

Group Art Unit: 1633

Continuation of

Serial No.

09/171,086

Examiner: Wilson, M.

Filed

January 22, 1999

For

HETEROLOGOUS BOOSTING IMMUNIZATIONS

PRELIMINARY AMENDMENT

Commissioner for Patents **Box Patent Application** Washington, D.C. 20231

Dear Sir:

Prior to examination and calculation of the filing fee, please amend the application as follows.

IN THE CLAIMS

Please amend the following claims:

- 1. (amended) A method for inducing an enhanced immunological response against at least one antigen in a mammal using heterologous boosting immunization, said method comprising the steps of:
- inoculating the mammal with a first recombinant vector comprising a DNA vector and a gene encoding said antigen; and

- inoculating the mammal with a boosting immunization with a second recombinant vector comprising a second DNA vector and the gene encoding said antigen, wherein said second DNA vector is different from said first DNA vector, thereby inducing an enhanced immunological response.
- 2. (amended) The method according to claim 1, wherein the first recombinant vector comprises a recombinant vaccinia virus vector.
- 3. (amended) The method according to claim 1, wherein the first recombinant vector comprises a recombinant fowlpox virus vector.
- 4. (amended) The method according to claim 1, wherein the first recombinant vector comprises an adenovirus vector.
- 5. (amended) The method according to claim 1, wherein the recombinant vectors further comprise a gene encoding an immunostimulatory molecule.
- 6. (amended) The method according to claim 1, wherein the second recombinant vector comprises a recombinant vaccinia virus vector.
- 7. (amended) The method according to claim 1 wherein the second recombinant vector comprises a recombinant fowlpox virus vector.
- 9. (amended) A method for treatment of a cancer patient using heterologous boosting immunization as immunotherapy, said method comprising the steps of:

2 EK784975391US

- immunizing said patient with an effective amount of a first recombinant vector comprising a first viral vector and a gene encoding a tumor-associated antigen; and
- boosting said patient with an effective amount of a second recombinant vector comprising a second viral vector and the gene encoding the tumor-associated antigen, wherein said second viral vector is different from said first viral vector, thereby treating said patient.
- 10. (amended) The method according to claim 9, wherein the tumor-associated antigen comprises gp100.
- 11. (amended) The method according to claim 9, wherein the tumor-associated antigen comprises MART-1.
- 12. (amended) The method according to claim 9, wherein the tumor-associated antigen comprises TRP-1.
- 13. (amended) The method according to claim 9, wherein the tumor-associated antigen comprises TRP-2.
- 14. (amended) The method according to claim 9, wherein the recombinant vectors further comprise a gene encoding an immunostimulatory molecule.
- 15. (amended) The method according to claim 9, wherein the first viral vector comprises a vaccinia virus.

- 16. (amended) The method according to claim 9, wherein the first viral vector comprises a fowlpox virus.
- 17. (amended) The method according to claim 9, wherein the first viral vector comprises an adenovirus.
- 18. (amended) The method according to claim 9, wherein the second viral vector comprises a vaccinia virus.
- 19. (amended) The method according to claim 9, wherein the second viral vector comprises fowlpox virus.
- 20. (amended) The method according to claim 9, wherein the second viral vector comprises an adenovirus.

REMARKS

Applicants respectfully request favorable consideration of the present application and claims. Early and favorable action by the Examiner is earnestly solicited.

No additional fee is believed to be necessary.

The Commissioner is hereby authorized to charge any additional fees which may be required for this amendment, or credit any overpayment to Deposit Account No. 13-4500, Order No. 2026-4231US2.

In the event that an extension of time is required, or which may be required in addition to that requested in a petition and for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response

timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. 13-4500, Order No. 2026-4231US2 A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

Respectfully submitted,

MORGAN & FINNEGAN, L.L.P.

Date: April 20, 2001

Dorothy R. Auth

Registration No. 36,434

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APPENDIX

- 1. (amended) <u>A method</u> [The use of a heterologous boosting immunization] for inducing an enhanced immunological response against at least one antigen in a mammal using heterologous boosting immunization, said [use] method comprising the steps of:
- inoculating the mammal with a first recombinant vector comprising a DNA vector and a gene encoding said antigen; and
- inoculating the mammal with a boosting immunization with a second recombinant vector comprising a second DNA vector and the gene encoding said antigen, wherein said second DNA vector is different from said first DNA vector, thereby inducing an enhanced immunological response.
- 2. (amended) The <u>method</u> [use of the immunization] according to claim 1, wherein the first recombinant vector comprises a recombinant vaccinia virus vector.
- 3. (amended) The <u>method</u> [use of the immunization] according to claim 1, wherein the first recombinant vector comprises a recombinant fowlpox virus vector.
- 4. (amended) The <u>method</u> [use of the immunization] according to claim 1, wherein the first recombinant vector comprises an adenovirus vector.
- 5. (amended) The method [use of the immunization] according to claim 1, wherein the recombinant vectors further comprise a gene encoding an immunostimulatory molecule.

- 6. (amended) The <u>method</u> [use of the immunization] according to claim 1, wherein the second recombinant vector comprises a recombinant vaccinia virus vector.
- 7. (amended) The <u>method</u> [use of the immunization] according to claim 1 wherein the second recombinant vector comprises a recombinant fowlpox virus vector.
- 9. (amended) A method [The use of a heterologous boosting immunization as immunotherapy] for treatment of a cancer patient using heterologous boosting immunization as immunotherapy, said method [use] comprising the steps of:
- immunizing said patient with an effective amount of a first recombinant vector comprising a first viral vector and a gene encoding a tumor-associated antigen; and
- boosting said patient with an effective amount of a second recombinant vector comprising a second viral vector and the gene encoding the tumor-associated antigen, wherein said second viral vector is different from said first viral vector, thereby treating [prolonging survival of] said patient.
- 10. (amended) The <u>method</u> [use of the immunization] according to claim 9, wherein the tumor-associated antigen comprises gp100.
- 11. (amended) The <u>method</u> [use of the immunization] according to claim 9, wherein the tumor-associated antigen comprises MART-1.

- 12. (amended) The <u>method</u> [use of the immunization] according to claim 9, wherein the tumor-associated antigen comprises TRP-1.
- 13. (amended) The <u>method</u> [use of the immunization] according to claim 9, wherein the tumor-associated antigen comprises TRP-2.
- 14. (amended) The <u>method</u> [use of the immunization] according to claim 9, wherein the recombinant vectors further comprise a gene encoding an immunostimulatory molecule.
- 15. (amended) The <u>method</u> [use of the immunization] according to claim 9, wherein the first viral vector comprises a vaccinia virus.
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- 19. (amended) The <u>method</u> [use of the immunization] according to claim 9, wherein the second viral vector comprises fowlpox virus.

20. (amended) The <u>method</u> [use of the immunization] according to claim 9, wherein the second viral vector comprises an adenovirus.

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- inoculating the mammal with a boosting immunization with a second recombinant vector comprising a second DNA vector and the gene encoding said antigen, wherein said second DNA vector is different from said first DNA vector, thereby inducing an enhanced immunological response.
- 2. (amended) The method according to claim 1, wherein the first recombinant vector comprises a recombinant vaccinia virus vector.
- 3. (amended) The method according to claim 1, wherein the first recombinant vector comprises a recombinant fowlpox virus vector.
- 4. (amended) The method according to claim 1, wherein the first recombinant vector comprises an adenovirus vector.
- 5. (amended) The method according to claim 1, wherein the recombinant vectors further comprise a gene encoding an immunostimulatory molecule.
- 6. (amended) The method according to claim 1, wherein the second recombinant vector comprises a recombinant vaccinia virus vector.
- 7. (amended) The method according to claim 1 wherein the second recombinant vector comprises a recombinant fowlpox virus vector.
- 9. (amended) A method for treatment of a cancer patient using heterologous boosting immunization as immunotherapy, said method comprising the steps of:

- immunizing said patient with an effective amount of a first recombinant vector comprising a first viral vector and a gene encoding a tumor-associated antigen; and
- boosting said patient with an effective amount of a second recombinant vector comprising a second viral vector and the gene encoding the tumor-associated antigen, wherein said second viral vector is different from said first viral vector, thereby treating said patient.
- 10. (amended) The method according to claim 9, wherein the tumor-associated antigen comprises gp100.
- 11. (amended) The method according to claim 9, wherein the tumor-associated antigen comprises MART-1.
- 12. (amended) The method according to claim 9, wherein the tumor-associated antigen comprises TRP-1.
- 13. (amended) The method according to claim 9, wherein the tumor-associated antigen comprises TRP-2.
- 14. (amended) The method according to claim 9, wherein the recombinant vectors further comprise a gene encoding an immunostimulatory molecule.
- 15. (amended) The method according to claim 9, wherein the first viral vector comprises a vaccinia virus.

3

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- 16. (amended) The method according to claim 9, wherein the first viral vector comprises a fowlpox virus.
- 17. (amended) The method according to claim 9, wherein the first viral vector comprises an adenovirus.
- 18. (amended) The method according to claim 9, wherein the second viral vector comprises a vaccinia virus.
- 19. (amended) The method according to claim 9, wherein the second viral vector comprises fowlpox virus.
- 20. (amended) The method according to claim 9, wherein the second viral vector comprises an adenovirus.

REMARKS

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By:

Respectfully submitted,

MORGAN & FINNEGAN, L.L.P.

Date: April 20, 2001

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- inoculating the mammal with a first recombinant vector comprising a DNA vector and a gene encoding said antigen; and
- inoculating the mammal with a boosting immunization with a second recombinant vector comprising a second DNA vector and the gene encoding said antigen, wherein said second DNA vector is different from said first DNA vector, thereby inducing an enhanced immunological response.
- 2. (amended) The <u>method</u> [use of the immunization] according to claim 1, wherein the first recombinant vector comprises a recombinant vaccinia virus vector.
- 3. (amended) The <u>method</u> [use of the immunization] according to claim 1, wherein the first recombinant vector comprises a recombinant fowlpox virus vector.
- 4. (amended) The <u>method</u> [use of the immunization] according to claim 1, wherein the first recombinant vector comprises an adenovirus vector.
- 5. (amended) The <u>method</u> [use of the immunization] according to claim 1, wherein the recombinant vectors further comprise a gene encoding an immunostimulatory molecule.

- 6. (amended) The <u>method</u> [use of the immunization] according to claim 1, wherein the second recombinant vector comprises a recombinant vaccinia virus vector.
- 7. (amended) The <u>method</u> [use of the immunization] according to claim 1 wherein the second recombinant vector comprises a recombinant fowlpox virus vector.
- 9. (amended) A method [The use of a heterologous boosting immunization as immunotherapy] for treatment of a cancer patient using heterologous boosting immunization as immunotherapy, said method [use] comprising the steps of:
- immunizing said patient with an effective amount of a first recombinant vector comprising a first viral vector and a gene encoding a tumor-associated antigen; and
- boosting said patient with an effective amount of a second recombinant vector comprising a second viral vector and the gene encoding the tumor-associated antigen, wherein said second viral vector is different from said first viral vector, thereby <u>treating</u> [prolonging survival of] said patient.
- 10. (amended) The method [use of the immunization] according to claim 9, wherein the tumor-associated antigen comprises gp100.
- 11. (amended) The <u>method</u> [use of the immunization] according to claim 9, wherein the tumor-associated antigen comprises MART-1.

- 12. (amended) The <u>method</u> [use of the immunization] according to claim 9, wherein the tumor-associated antigen comprises TRP-1.
- 13. (amended) The <u>method</u> [use of the immunization] according to claim 9, wherein the tumor-associated antigen comprises TRP-2.
- 14. (amended) The <u>method</u> [use of the immunization] according to claim 9, wherein the recombinant vectors further comprise a gene encoding an immunostimulatory molecule.
- 15. (amended) The method [use of the immunization] according to claim 9, wherein the first viral vector comprises a vaccinia virus.
- 16. (amended) The method [use of the immunization] according to claim 9, wherein the first viral vector comprises a fowlpox virus.
- 17. (amended) The method [use of the immunization] according to claim 9, wherein the first viral vector comprises an adenovirus.
- 18. (amended) The method [use of the immunization] according to claim 9, wherein the second viral vector comprises a vaccinia virus.
- 19. (amended) The method [use of the immunization] according to claim 9, wherein the second viral vector comprises fowlpox virus.

20. (amended) The <u>method</u> [use of the immunization] according to claim 9, wherein the second viral vector comprises an adenovirus.